

Remarks

Claims 1, 8, 14 and 23 have been amended.

Claims 24-26 have been added.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (emphasis added).

Claims 1-4, 7, 20-22

Claim 1 has been amended to claim “a one-piece anastomosis device for connecting a graft vessel to a target vessel, comprising a device body formed of a superelastic or pseudoelastic material, the body having an insertion configuration and a tissue holding configuration in which the body has an inner flange and an outer flange, the outer flange having a plurality of outer flange members and the inner flange having a plurality of inner flange members, wherein at least one of the outer flange members is substantially radially offset from at least one of the inner flange members in the tissue holding configuration; and wherein at least a portion of the body between the inner flange and the outer flange maintains a substantially constant diameter in both the insertion configuration and the tissue holding configuration.”

In contrast, U.S. Pat. No. 6,428,550 to Vargas (“Vargas”) discloses a one-piece anastomosis device wherein the entire body between the inner flange and the outer flange expands from a first diameter to a second diameter. (e.g., column 4, line 67 through column 5, line 2; column 5, lines 44-47; column 6, lines 36-40; column 8, lines 54-57; Figures 16-17).

Thus, Vargas neither expressly or inherently describes each and every element of amended claim 1.

The Office Action also rejected claim 1 under U.S. Pat. No. 6,599,303 to Peterson ("Peterson '303"). As with Vargas, Peterson '303 discloses a one-piece anastomosis device wherein the entire body between the inner flange and the outer flange expands from a first diameter to a second diameter. (*e.g.*, column 9, lines 40-48; column 15, lines 37-39; column 16, lines 59-61; column 17, lines 52-56; Figures 13, 30, 37, 41). Thus, Peterson '303 neither expressly or inherently describes each and every element of amended claim 1.

Claim 1 was rejected as well under U.S. Pat. No. 6,152,937 to Peterson ("Peterson '937"). Peterson '303 is a continuation of Peterson '937, and thereby contains the same disclosure as its parent Peterson '937. Thus, Peterson '937 neither expressly nor inherently describes each and every element of amended claim 1.

The Office Action rejected claim 1 under 35 U.S.C. §102(e) as being anticipated by Nobis et. al., U.S. Pat. No. 6,605,098 ("Nobis"). The statute 35 U.S.C. §102(e) states that:

A person shall be entitled to a patent unless...(e) the invention was described in...(2) a patent granted on an application for patent by another filed in the United States before the application for patent.

Thus, the critical reference date of an issued U.S. patent under 35 U.S.C. §102(e) is its filing date. (MPEP 2136). Nobis was filed on September 28, 2001, so that is its critical reference date. However, the present application was filed on October 12, 2000, prior to the critical reference date of Nobis. Thus, Nobis is not prior art under 35 U.S.C. §102(e). As a result, Applicants request withdrawal of the rejection of claim 1 and its dependent claims under Nobis.

Neither Vargas, Peterson '303 nor Peterson '937 expressly or inherently describes each and every element claimed in amended claim 1. Further, Nobis is not prior art to this

application. Applicants consequently believe claim 1 is in condition for allowance. Claims 2-4, 7, and 20-22 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well.

Claims 8-13

Claim 8 has been amended to claim “a tube deployed anastomosis system for connecting a graft vessel to a target vessel, comprising a deployment tube; and an anastomosis device formed of a superelastic or pseudoelastic material, the device having an insertion configuration and a tissue holding configuration in which the device has an inner flange and an outer flange, the outer flange having a plurality of outer flange members and the inner flange having a plurality of inner flange members, wherein at least one of the outer flange members is substantially radially offset from at least one of the inner flange members in the tissue holding configuration, and wherein at least a portion of the body between the inner flange and the outer flange maintains a substantially constant diameter in both the insertion configuration and the tissue holding configuration; wherein at least one of the inner and outer flanges is radially constrained in the deployment tube in the insertion configuration for insertion into the target vessel and when released from the deployment tube self deforms to the tissue holding configuration.”

The discussion above with respect to amended claim 1 applies equally here. Neither Vargas, Peterson ‘303 nor Peterson ‘937 expressly or inherently describes each and every element claimed in amended claim 8. Further, Nobis is not prior art to this application. Applicants consequently believe claim 8 is in condition for allowance. Claims 9-13 depend directly or indirectly from claim 8, and are thus believed to be in condition for allowance as well.

Claims 14-19

Claim 14 has been amended to claim “a method of deploying an anastomosis system for connecting a graft vessel to a target vessel, the method comprising providing an anastomosis device deployable to form an inner flange having a plurality of inner flange members and an outer flange having a plurality of outer flange members; penetrating and holding the graft vessel with at least one of the inner flange members; and deploying the one piece device by self deformation to a tissue holding configuration in which the device has an inner flange and an outer flange and traps the target vessel tissue between the inner flange and the outer flange, wherein at least one of the outer flange members is substantially radially offset from at least one of the inner flange members, and wherein at least a portion of the device between the inner flange and the outer flange maintains a substantially constant diameter before and after the deploying.”

The discussion above with respect to amended claim 1 applies equally here. Neither Vargas, Peterson ‘303 nor Peterson ‘937 expressly or inherently describes each and every element claimed in amended claim 14. Further, Nobis is not prior art to this application. Applicants consequently believe claim 14 is in condition for allowance. Claims 15-19 depend directly or indirectly from claim 14, and are thus believed to be in condition for allowance as well.

Claims 23-26

Claim 23 has been amended to claim “a one-piece anastomosis device for connecting a graft vessel to a target vessel, comprising a device body formed of a shape memory material, the body having an insertion configuration and a tissue holding configuration in which the body has an inner flange and an outer flange, the outer flange having a plurality of outer flange members and the inner flange having a plurality of inner flange members, wherein at

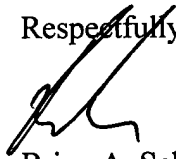
least one of the two sets of flange members does not penetrate tissue; and wherein at least a portion of the body between the inner flange and the outer flange maintains a substantially constant diameter in both the insertion configuration and the tissue holding configuration.”

The discussion above with respect to amended claim 1 applies equally here. Neither Vargas, Peterson ‘303 nor Peterson ‘937 expressly or inherently describes each and every element claimed in amended claim 23. Further, Nobis is not prior art to this application. Applicants consequently believe claim 23 is in condition for allowance. Claims 24-26 depend from claim 23, and are thus believed to be in condition for allowance as well.

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar
Attorney for Applicants
Reg. No. 45,076
Tel. No. (650) 331-7162
Chief Patent Counsel
Cardica, Inc.